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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER

FORD, JOHN M

ART UNIT	PAPER NUMBER
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1624

DATE MAILED: 10/25/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No. <u>19/086157</u>	Applicant(s) <u>N. Bartiedal</u>
Examiner <u>J.M. Ford</u>	Group Art Unit <u>1624</u>

—The MAILING DATE of this communication appears on the cover sheet beneath the correspondence address—

P r i d f r Response

A SHORTENED STATUTORY PERIOD FOR RESPONSE IS SET TO EXPIRE THREE MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a response be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for response specified above is less than thirty (30) days, a response within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for response is specified above, such period shall, by default, expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to respond within the set or extended period for response will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).

Status

- ☐ Responsive to communication(s) filed on _____.
- ☐ This action is **FINAL**.
- ☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disp sition of Claims

- ☒ Claim(s) 1 - 116 is/are pending in the application.
- ☐ Of the above claim(s) _____ is/are withdrawn from consideration.
- ☐ Claim(s) _____ is/are allowed.
- ☒ Claim(s) 1 - 116 is/are rejected.
- ☐ Claim(s) _____ is/are objected to.
- ☐ Claim(s) _____ are subject to restriction or election requirement.

Application Papers

- ☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.
- ☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.
- ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.
- ☐ The specification is objected to by the Examiner.
- ☐ The oath or declaration is objected to by the Examiner.

Pri rity under 35 U.S.C. § 119 (a)-(d)

- ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
 - ☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been received.
 - ☐ received in Application No. (Series Code/Serial Number) _____.
 - ☐ received in this national stage application from the International Bureau (PCT Rule 1.7.2(a)).

*Certified copies not received: _____.

Attachm nt(s)

- ☒ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____
- ☐ Notice of References Cited, PTO-892
- ☐ Notice of Draftsperson's Patent Drawing Review, PTO-948
- ☐ Interview Summary, PTO-413
- ☐ Notice of Informal Patent Application, PTO-152
- ☐ Other _____

Office Acti n Summary

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There are 116 claims in this application. A true burden we are given only a few hours to work on any given application.

Lamotrigine is not an IUPAC name. The classification and search is based on the as-triazine name - the application cannot be allowed with the trade name. A close compound can only be found by means of the IUPAC name.

Page 1 of the specification indicates the as-triazine in question, here, is known, as well as crystallographic structure.

The USPTO does not have Labs. We cannot determine that the various physical forms claimed here are not present in the prior art.

Therefore, claims 1--16 are rejected under 35 U.S.C. 102 as inherent in the prior art.

Claim 1 is rejected under 35 U.S.C. 112, 2nd paragraph. What is the chemical structure of the claimed solvate?

Claims 5, 10, 15, 20, 25, 30, 35, 40, 45, 50, 60, et seq. are rejected under 35 U.S.C. 112, 2nd paragraph, as they contain reference to a drawing fig.

Claims must be complete within themselves.

The following is from "Chemical Patent Practice" by John L. White (1998 Edition).

(iii) Purer Forms of Old Products [See Section IIDI(c)(I)]

Where the pure material has the same usefulness or assortment of properties is one of the factors to be considered in determining the issue of its obviousness over the form it existed in the prior art. In re Bergstrom et al. (CCPA 1970) 427 F2d 394, 166 USPQ 256. Thus, a pure

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compound can, under certain conditions, be patentable over the same compound in impure form, Ex parte Stern (BPAI 1989) 13 PQ2d 1379; In re Williams (CCPA 1948) 171 F2d 319, 80 USPQ 150, e.g., when a far greater yield of antibiotic is obtained with less reagent when the pure form is acylated, In re Doyle et al. (CCPA 1964) 327 F2d 513, 140 USPQ 421, or where a method for producing the claimed crystalline anhydrous form of the compound was not obvious, even assuming one skill in duction. In re Irani et al. (CCPA 1970) 427 F2d 806, 166 USPQ 24. Accord, Ex parte Reed et al. (POBA 1961) 135 USPQ 105; Ex parte Conn et al. (POBA 1955) 119 USPQ 388; Ex parte Yale et al. (POBA 1958) 119 USPQ 256. Compare, Ex parte Steelmand (POBA 1962) 140 USPQ 189.

However, where the purification of an old product results in a mere change in degree in its properties, the purified form is not patentable. Ex parte Windhaus (POBA 1931) 15 USPQ 45, (product having Vitamin D activity, separated from the parent alumina); In re Merz (CCPA 1938) 97 F2d 599, 38 USPQ 143, (artificial ultramarine, substantially free from color dulling floating impurities); In re Macallum et al. (CCPA 1939) 107 F2d 618, 43 USPQ 400, (pure Vitamin C); Ex parte Sparhawk (POBA 1945) 64 USPQ 339, (musk-like extract of muskrat gland); In re Weijlard et al. (CCPA 1946) 154 F2d 133, 69 USPQ 86, (non-hygroscopic, crystalline form of amorphous prior art compound); IN re Johnson et al. (CCPA 1938) 94 F2d 978, 37 USPQ 75, (stable, purified concentrated borate ore); Ex parte Caviollito (POBA 1950) 89 USPQ 449, (antibiotic isolated from garlic); Ex parte Snell (adrenal gland stimulating concentrate); Ex parte Hartop (POBA 1962) 139 USPQ 525, (stable, pure crystalline

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thiobarbiturate salts); Ex parte Siddiqui characteristic of an old product does not render the novel form patentable where the difference in form, purity or characteristic was inherent in or rendered obvious by the prior art. In re Cofer (CCPA 1966) 354 F2d 664, 148 USPQ 268.

A mere difference in degree of toxicity in the purified form of an antibiotic existing in a prior art mixture of antibiotics is not sufficient to render the pure product patentable. Ex parte Schmidt-Kastner et al. (POBA 1963) 153 USPQ 473. However, a pure product has been held patentable where the prior art form was not suited to the utility of the claimed product.

Farbenfabriken of Elberfeld Co. v. Kuehmsted (CA 7 1910) 171 F 887, aff'd, 179 F 701, (the aspirin case); Binney & Smith Co. v. United Carbon Co. Et A. (CA 4 1942) 125 F2d 255; 52 USPQ 205; Ex parte Parke et al. (POBA 1944) 64 USPQ 335.

The pure crystalline form of Vitamin c was held unpatentable over natural sources thereof, the difference in degree of purity itself being insufficient to establish patentability. In re King et al. (CCPA 1939) 107 F2d 618, 43 USPQ 400.

Tables of data do not impart a structure in claims 3, 9, 14, 19, etc, et seq. It would require undue experimentation to determine the structure (35 U.S.C. 112 2nd paragraph).

A variation in form does not, in itself, impart patentability; Glue Co. v. Upton (USCC 1878) 97 US 3.

Reciting an old composition in a new physical form only incidentally related to its unobvious utility will not impart patentability thereto. In re Haller (CCPA 1947) 161 F2d 280, 73 USPQ 403.

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Where the utility of the new form of the old material is no different than that of the old form, the new form is ordinarily unpatentable over the old. Ex parte Hartop (POBA 1962) 139 USPQ 525.

We have no way of determining the structure of the compound claimed in claim 2. A combination product-by-process claim may be helpful. What is the structure of the compound of claim 2?² How was that compound obtained? Claims 2, 7, 12, 17, 22, 27, 32, 37, 42, 47, 52, 57 et seq. are rejected under 35 U.S.C. 112, 2nd paragraph. We have no way of determining what the structure claimed really is.

What is the structure of the solvate claimed in claims 6, 11, 16, 21, 26, 31, 36, 41 et seq. what is the structure of the solvate?² What is bonded to what?² Claims 6, 11, 16, 21, 26, 36, 41, et seq are rejected under 35 U.S.C. 112, as unclear.

Claim 92 is not a proper composition claim as it does not recite an inert carrier. Claim 92 is rejected under 35 U.S.C. 112, 2nd paragraph, as we do not know what forms B, C, D, E, E1, F, H, J, K, L, M, N, O, P, Q, R, S, and U are.

Claims 92 and 93 are rejected under 35 U.S.C. 103. With that many forms of the s-triazine recited, it must surely include the prior art.

John M. Ford:jmr

October 23, 2002

JOHN M. FORD
PRIMARY EXAMINER*Greg Reid Unit 1624*